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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,838	06/14/2006	Lars Lilljequist	1103326-0910	5010
7470	7590	07/13/2007		
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER RAHMANI, NILOOFAR	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,838

Applicant(s)

LILLJEQUIST ET AL.

Examiner

Niloofer Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29, 31, 32, 35, 36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15-20, 27-29, 31, 32, 35, 36 and 38 is/are rejected.
- 7) ☒ Claim(s) 3-14 and 21-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-29, 31-32, 35-36, and 38 are pending in the instant application and claims 30, 33-34, and 37 are cancelled.

Priority

2. This application is filed on 06/14/2006, which is a 371 of PCT/SE04/01909, filed on 12/16/2004, which claims priority of SWEDEN 0303451-9, filed on 12/18/2003.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-20 are rejected because the terms "higher temperature and lower temperature" are confusing. The temperature is higher or lower than what temperature? Correction is required.

4. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "preparation" is confusing. How are these claims different from the routine purification steps. Correction is required.

5. ***Claim Rejections - 35 USC § 112***

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29,31-32,35-36, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

- 1) The breadth of the claims.
- 2) The nature of the invention,
- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,

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8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to a method of treating or inhibiting a gastrointestinal disorder using the mesylate salt of the compound in claim 1.

The state of the prior art: " Dialkylamine derivatives which contain an alkyl radical substituted by an alkoxy, alkylthio or alkylamino group containing an monocyclic or bicyclic hydrocarbon radical, and an alkyl radical bearing an optionally substituted phenyl group and its pharmaceutical compositions are using to protect the gastrointestinal mucosa and inhibit ulcers, while being readily tolerated and exhibiting low toxicity."(Hell et al., US 5,294,638)

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the salt of the compound of formula of claim 1 would be useful for treating a pharmacological condition in a subject.

Amount of guidance/working examples: On the specification, applicant has no examples of test compounds for treating gastrointestinal disorder. However,

applicant has not guidance or examples for treating disorder of respiratory, and gastrointestinal system.

The breadth of the claims: The breadth of claims is drawn to a method of treating or inhibiting a gastrointestinal disorder using the mesylate salt of the compound in claim 1.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating disorder of the respiratory, and gastrointestinal systems, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 29,31-32,35-36, and 38, for treating gastrointestinal disease, have been enabled by the instant specification.

6. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

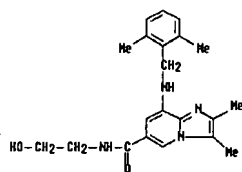
Claims 1-2, 15-17, 27-29, 31-32, 35-36, and 38 are rejected under 103(a) as being unpatentable over Hanauer et al. of WO 2003094967.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hanauer et al. disclosed the instant compound, pharmaceutical composition, and method of using the compound, which the compound from the STN search is

RN 248919-64-4

CN Imidazo[1,2-a]pyridine-6-carboxamide, 8-[[[(2,6-dimethylphenyl)methyl]amino]-N-(2-hydroxyethyl)-2,3-dimethyl-



, and the invention includes not only the active compounds, but also their pharmaceutically acceptable salts.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art claims is that the prior art do not include the specific mesylate salt as the instant claims.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the salt of the compound of Hanauer et al. with a reasonable expectation to obtain the instant mesylate salt. Because changing one salt to other is within the skill of artisan and mesylate is a common salt.

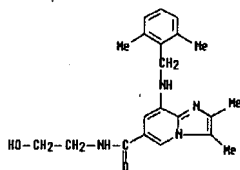
7. Claims 1-2, 15-17, 27-29, 31-32, 35-36, and 38 are rejected under 103(a) as being unpatentable over Juppo et al. of WO 02/064118.

Determination of the scope and content of the prior art (MPEP §2141.01)

Juppo et al. disclosed the instant compound, pharmaceutical composition, and method of using the compound, which the compound from the STN search is

RN 248919-64-4

CN Imidazo[1,2-a]pyridine-6-carboxamide, 8-[[[(2,6-dimethylphenyl)methyl]amino]-N-(2-hydroxyethyl)-2,3-dimethyl-



; and the

invention includes not only the active compounds, but also their pharmaceutically acceptable salts.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art claims is that the prior art do not include the specific mesylate salt as the instant claims.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the salt of the compound of Juppo et al. with a reasonable expectation to obtain the instant mesylate salt. Because changing one salt to other is within the skill of artisan and mesylate is a common salt.

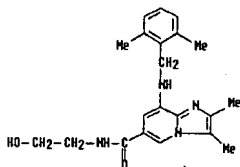
8. Claims 1-2, 15-17, 27-29, 31-32, 35-36, and 38 are rejected under 103(a) as being unpatentable over Elman et al. of WO 02/20523.

Determination of the scope and content of the prior art (MPEP §2141.01)

Elman et al. disclosed the instant compound, pharmaceutical composition, and method of using the compound, which the compound from the STN search is

RN 248919-64-4

CN Imidazo[1,2-a]pyridine-6-carboxamide, 8-[[[(2,6-dimethylphenyl)methyl]amino]-N-(2-hydroxyethyl)-2,3-dimethyl-



, and the invention includes not only the active compounds, but also their pharmaceutically acceptable salts.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art claims is that the prior art do not include the specific mesylate salt as the instant claims.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the salt of the compound of Elman et al. with a reasonable expectation to obtain the instant

mesylate salt. Because changing one salt to other is within the skill of artisan and mesylate is a common salt.

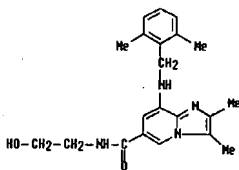
9. Claims 1-2, 15-17, 27-29, 31-32, 35-36, and 38 are rejected under 103(a) as being unpatentable over Amin et al. of WO 99/55706.

Determination of the scope and content of the prior art (MPEP §2141.01)

Amin et al. disclosed the instant compound, pharmaceutical composition, and method of using the compound, which the compound from the STN search is

RN 248919-64-4

CN Imidazo[1,2-a]pyridine-6-carboxamide, 8-[[[(2,6-dimethylphenyl)methyl]amino]-N-(2-hydroxyethyl)-2,3-dimethyl-



, and the invention includes not only the active compounds, but also their pharmaceutically acceptable salts.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art claims is that the prior art do not include the specific mesylate salt as the instant claims.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the salt of the compound of Amin et al. with a reasonable expectation to obtain the instant mesylate salt. Because changing one salt to other is within the skill of artisan and mesylate is a common salt.

10.

Claim Objections

Claims 3-14, and 21-26 are objected to as being dependent upon a cancelled base claims 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

07/11/2007

NK



MARGARET D. SEAMAN

PRIMARY EXAMINER

GROUP 1625